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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,319	11/06/2003	Ranjan Perera	ARBG-004/07US (307197-203)	7997
58249	7590	12/01/2006	EXAMINER	
COOLEY GODWARD KRONISH LLP THE BROWN BUILDING - 875 15TH STREET, NW SUITE 800 WASHINGTON, DC 20005-2221			QIAN, CELINE X	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/702,319

Applicant(s)

PERERA ET AL.

Examiner

Celine X. Qian Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Claims 1-15 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on Group I is acknowledged. The traversal is on the ground(s) that a search of sequences SEQ ID NO: 113, SEQ ID NO: 60 and SEQ ID NO:12 would not be burdensome because the latter are part of SEQ ID NO: 113. Applicants further argue that a search of Groups I-III with regard to the elected sequences would not be burdensome because the invention of Groups II and III are related to Group I because plant is produced by transforming the plant with the genetic construct of Group I. Applicants further assert that the invention of Groups I and II are related as combination and subcombination, and the method of Group III comprises all the limitations of Group I, thus, a search of Groups I-III would not be burdensome.

The above arguments have been fully considered and deemed partially persuasive. Since SEQ ID NO: 12 and 60 are part of SEQ ID NO: 113, they will be examined together. However, with regard to the argument directed to Groups I-III, it is not found persuasive because the invention of Groups I-II are not related as combination and subcombination. The plant of Group II comprises a genetic construct of claim 4 or 8, however, the invention of Group I is not limited to specific sequences as recited in claim 4 and 8. For example, claim 1 is directed to a *E. grandis* cOMT promoter. For reasons set forth in the previous office action, although the isolated nucleotide and the plant are related, they are not obvious variants of each other. Therefore, the invention of Groups I and II are patentably distinct from each other. Further, the invention of

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Groups I and III are patentably distinct because the invention of Group I can be used in other processes. They will be rejoined only when the invention of Group I are found allowable.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 12-15 are withdrawn from consideration for being directed to non-elected subject matter. Claims 1-11 are currently under examination.

Priority

The instant application is a CIP to a number of applications. A search of the sequence SEQ ID NO:113 and its fragments, SEQ ID NO: 12 & 60 reveals that the sequences are first disclosed in application 09/724,624. Therefore, the priority date to which the claims that directed to these sequences is the filing date of this application, 11/28/2000.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is set forth by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the invention. . .[emphasis

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added].” The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that “as of the filing date sought, [the inventor] was in possession of the invention.” See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in “possession” of the invention claimed by describing the invention with all of its claimed limitations “by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

In analyzing whether the written description requirement is met, it is first determined whether a representative number of species have been described by their complete structure. Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. Claims 1, 3, 9 and 11 recite a functional vascular tissue specific *E. grandis* cOMT promoter. It is well known in the art that promoter, in other words, the transcription regulatory element of a specific gene may be 5’ or 3’ UTR, or within the intronic region of the gene, or in sequences that are distal to the gene. As such, the claimed genus of nucleic acid encompass a large number of sequences of various length and various structure (sequence) proximal to distal to the *E. grandis* cOMT gene. The instant specification only discloses that the sequences from the 5’UTR of cOMT gene, particularly, SEQ ID NO: 113 and one fragment, SEQ ID NO: 12, which have the vascular tissue specific regulatory function. The specification fails to disclose promoter sequences from other region of the *E. grandis* cOMT gene, which has the vascular tissue specific regulatory function. The specification also fails to disclose whether other fragments of SEQ ID NO: 113 (either longer or

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shorter than SEQ ID NO: 12) that have the claimed vascular tissue specific regulatory function. Moreover, the specification does not disclose what necessary element is required for the claimed function. Similarly, regarding claim 2, the specification fails to disclose any sequence that is hybridizable, having 75%-90% homology with SEQ ID NO: 113, SEQ ID NO: 12 or nucleotide 1019-1643, or is 20-600 mer of the above sequences which has the vascular specific promoter function. Regarding claims 4-8 and 10, the claims recite the fragment of 1019-1643. The instant specification does not disclose whether this fragment of has vascular specific promoter activity. Therefore, in view of the claimed broad genus, and the limited disclosure of the instant specification, the description in the instant specification is not adequate to support the claimed genus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4-8, 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 2 and 4, the recitation of "the sequences recited in SEQ ID NO: 12 and SEQ ID NO: 113, nucleotides 1019-1643" render the claims indefinite because it is unclear nucleotides 1019-1643 is part of SEQ ID NO: 12, 113 or other sequences. Further, it is unclear what "recite" the sequences in SEQ ID NO: 12 and 113. As such, the metes and bonds of the claim cannot be established. Claims 5-8 and 10 are rejected because they depend on claim 4.

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Claim 11 recites the limitation "the host cell" in line 1. There is insufficient antecedent basis for this limitation in the claim because claim 9 is directed to a genetic construct, not a host cell.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by the sequence disclosed by De Melis et al (AF168777, disclosed on 8/19/1999).

The sequence of AF168777 has 162 contiguous sequence of SEQ ID NO: 113.
Therefore, it discloses the instantly claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

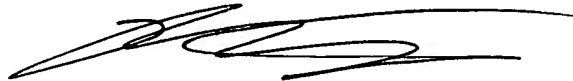
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.
Examiner
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CELINE QIAN, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to be 'C. Qian', written in a cursive style.